Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-87 (Cancelled).

88. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) adding to said biological material at least one stabilizer mixture in an amount effective to protect said biological material from said radiation; and

(ii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material;

wherein said effective rate is not constant and comprises a rate between 0.1 kGy/hr to 3.0 kGy/hr for at least a portion of said period of time and a rate of at least 6.0 kGy/hr for at least another portion of said period of time.

89. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) reducing the residual solvent content of said biological material;

(ii) adding to said biological material at least one stabilizer mixture; and

(iii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material, wherein the level of said residual solvent content and the amount of said stabilizer mixture are together effective to protect said biological material from said radiation, and further wherein steps (i) and (ii) may be performed in inverse order;

wherein said effective rate is not constant and comprises a rate between 0.1 kGy/hr to 3.0 kGy/hr for at least a portion of said period of time and a rate of at least 6.0 kGy/hr for at least another portion of said period of time.

90. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) reducing the temperature of said biological material;

(ii) adding to said biological material at least one stabilizer mixture; and

(iii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material, wherein the temperature and the amount of said stabilizer mixture are together effective to protect said biological material from said radiation, and further wherein steps (i) and (ii) may be performed in inverse order;

wherein said effective rate is not constant and comprises a rate between 0.1 kGy/hr to 3.0 kGy/hr for at least a portion of said period of time and a rate of at least 6.0 kGy/hr for at least another portion of said period of time.

91. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) reducing the residual solvent content of said biological material;

(ii) adding to said biological material at least one stabilizer mixture

(iii) reducing the temperature of said biological material; and

(iv) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material, wherein the temperature and the amount of said stabilizer mixture are together effective to protect said biological material from said radiation, and further wherein steps (i), (ii) and (iii) may be performed in any order;

wherein said effective rate is not constant and comprises a rate between 0.1 kGy/hr to

3.0 kGy/hr for at least a portion of said period of time and a rate of at least 6.0 kGy/hr for at least another portion of said period of time.

92. (New) The method according to claim 91, wherein said residual solvent content is less than 10%.

93. (New) The method according to claim 89, wherein said solvent is water.

94. (New) The method according to claim 93, wherein said residual solvent content is reduced by the addition of an organic solvent.

95. (New) The method according to claim 89, wherein said solvent is an organic solvent.

96. (New) The method according to claim 89, wherein said biological material is suspended in an organic solvent following reduction of said residual solvent content.

97. (New) The method according to claims 88, 89, 90 or 91, wherein said effective dose rate comprises a rate between 0.25 kGy/hr to 2.0 kGy/hr for at least a portion of said period of time and a rate of at least 6.0 kGy/hr for at least another portion of said period of time.

98. (New) The method according to claims 88, 89, 90 or 91, wherein said effective dose rate comprises a rate between 0.5 kGy/hr to 1.5 kGy/hr for at least a portion of said period of time and a rate of at least 6.0 kGy/hr for at least another portion of said period of time.

99. (New) The method according to claims 88, 89, 90 or 91, wherein said effective dose rate comprises a rate between 0.5 kGy/hr to 1.0 kGy/hr for at least a portion of said period of time and a rate of at least 6.0 kGy/hr for at least another portion of said period of time.

100. (New) The method according to claims 88, 89, 90 or 91, wherein said effective rate further comprises a rate of least 18.0 kGy/hour for at least another portion of said period of time.

101. (New) The method according to claims 88, 89, 90 or 91, wherein said effective rate further comprises a rate of least 30.0 kGy/hour for at least another portion of said period of time.

102. (New) The method according to claims 88, 89, 90 or 91, wherein said effective rate further comprises a rate of least 45 kGy/hour for at least another portion of said period of time.

103. (New) The method according to claims 88, 89, 90 or 91, wherein said biological material is maintained in a low oxygen atmosphere.

104. (New) The method according to claims 88, 89, 90 or 91, wherein said biological material is maintained in an atmosphere comprising at least one noble gas.

105. (New) The method according to claim 104, wherein said noble gas is argon.

106. (New) The method according to claims 88, 89, 90 or 91, wherein said biological material is maintained in a vacuum.

107. (New) The method according to claim 89, wherein said residual solvent content is reduced by a method selected from the group consisting of lyophilization, drying, concentration, addition of solute, evaporation, chemical extraction, spray-drying, and vitrification.

108. (New) The method according to claims 89 or 91, wherein said residual solvent content is less than 15%.

109. (New) The method according to claims 89 or 91, wherein said residual solvent content is less than 3%.

110. (New) The method according to claims 89 or 91, wherein said residual solvent content is less than 2%.

111. (New) The method according to claims 89 or 91, wherein said residual solvent content is less than 1%.

112. (New) The method according to claims 89 or 91, wherein said residual solvent content is less than 0.5%.

113. (New) The method according to claims 89 or 91, wherein said residual solvent content is less than 0.08%.

114. (New) The method according to claims 88, 89, 90 or 91, wherein at least one

sensitizer is added to said biological material prior to said step of irradiating said biological material.

115. (New) The method according to claims 88, 89, 90 or 91, wherein said stabilizer mixture comprises at least three stabilizers.

116. (New) The method according to claims 88, 89, 90 or 91, wherein said stabilizer mixture comprises at least one antioxidant.

117. (New) The method according to claims 88, 89, 90 or 91, wherein said stabilizer mixture comprises at least one free radical scavenger.

118. (New) The method according to claims 88, 89, 90 or 91, wherein said stabilizer mixture comprises at least one combination stabilizer.

119. (New) The method according to claims 88, 89, 90 or 91, wherein said stabilizer mixture comprises at least one ligand.

120. (New) The method according to claim 119, wherein said ligand is heparin.

121. (New) The method according to claims 88, 89, 90 or 91, wherein said stabilizer mixture comprises at least one stabilizer that reduces damage due to reactive oxygen species.

122. (New) The method according to claims 88, 89, 90 or 91, wherein said stabilizer mixture comprises at least one stabilizer selected from the group consisting of: ascorbic acid or a salt or ester thereof; glutathione; vitamin E or a derivative thereof; albumin; sucrose;

glycylglycine; L-carnosine; cysteine; silimarin; diosmin; hydroquinonesulfonic acid; 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; uric acid or a salt or ester thereof; methionine; histidine; N-acetyl cysteine; lipoic acid; sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof; propyl gallate; and mixtures of two or more thereof.

123. (New) The method according to claim 122, wherein said mixtures of two or more additional stabilizers are selected from the group consisting of: mixtures of ascorbic acid, or a salt or ester thereof, and uric acid, or a salt or ester thereof; mixtures of ascorbic acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and albumin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, albumin and sucrose; mixtures of ascorbic acid, or a salt or ester thereof, and glycylglycine; mixtures of ascorbic acid, or a salt or ester thereof, glycylglycine and albumin; mixtures of ascorbic acid, or a salt or ester thereof and L-carnosine; mixtures of ascorbic acid, or a salt or ester thereof and cysteine; mixtures of ascorbic acid, or a salt or ester thereof and N-acetyl cysteine; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and silymarin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and diosmin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and lipoic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and hydroquinonesulfonic acid; and mixtures of uric acid, or a salt or ester thereof, lipoic acid, sodium formaldehyde sulfoxylate, gallic acid or a derivative thereof, propyl gallate and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid.

124. (New) The method according to claims 88, 89, 90 or 91, wherein said stabilizer mixture comprises ascorbic acid or a salt or ester thereof.

125. (New) The method according to claims 88, 89, 90 or 91, wherein said radiation is corpuscular radiation or electromagnetic radiation, or a mixture thereof.

126. (New) The method according to claim 125, wherein said electromagnetic radiation is selected from the group consisting of radio waves, microwaves, visible and invisible light, ultraviolet light, x-ray radiation, gamma radiation and combinations thereof.

127. (New) The method according to claims 88, 89, 90 or 91, wherein said radiation is gamma radiation.

128. (New) The method according to claims 88, 89, 90 or 91, wherein said radiation is E-beam radiation.

129. (New) The method according to claims 88, 89, 90 or 91, wherein said radiation is visible light.

130. (New) The method according to claims 88, 89, 90 or 91, wherein said radiation is ultraviolet light.

131. (New) The method according to claims 88, 89, 90 or 91, wherein said radiation is x-ray radiation.

132. (New) The method according to claims 88, 89, 90 or 91, wherein said radiation is polychromatic visible light.

133. (New) The method according to claims 88, 89, 90 or 91, wherein said radiation is infrared.

134. (New) The method according to claims 88, 89, 90 or 91, wherein said radiation is a combination of one or more wavelengths of visible and ultraviolet light.

135. (New) The method according to claims 88, 89, 90 or 91, wherein said irradiation is conducted at ambient temperature.

136. (New) The method according to claims 88, 89, 90 or 91, wherein said irradiation is conducted at a temperature below ambient temperature.

137. (New) The method according to claims 88, 89, 90 or 91, wherein said irradiation is conducted below the freezing point of said biological material.

138. (New) The method according to claims 88, 89, 90 or 91, wherein said irradiation is conducted below the eutectic point of said biological material.

139. (New) The method according to claims 88, 89, 90 or 91, wherein said irradiation is conducted at a temperature above ambient temperature.

140. (New) A method of treating a disease or deficiency in a mammal comprising administering to a mammal in need thereof an effective amount of a biological preparation

which has been sterilized according to the method according to claims 88, 89, 90 or 91.

141. (New) The method according to claim 140, wherein said mammal is a human.

142. (New) The method according to claim 140, wherein said deficiency is Factor VIII deficiency.

143. (New) The method according to claim 140, wherein said disease responds to the administration of urokinase.

144. (New) The method according to claim 140, wherein said disease responds to the administration of thrombin.

145. (New) The method according to claim 140, wherein said deficiency is a glucosidase deficiency.

146. (New) The method according to claim 140, wherein said deficiency is a galactosidase deficiency.

147. (New) The method according to claim 146, wherein said deficiency is a Fabry's Disease.

148. (New) The method according to claim 140, wherein said deficiency is a sulfatase deficiency.

149. (New) The method according to claim 140, wherein said deficiency is an

Immunoglobulin deficiency.

150. (New) The method according to claim 140, wherein said disease responds to the administration of an Immunoglobulin.

151. (New) The method according to claim 140, wherein said disease responds to the administration of Factor VIII.

152. (New) A composition comprising at least one biological material and at least one flavonoid/flavonol stabilizer in an amount effective to preserve said biological material for its intended use following sterilization with radiation, wherein the residual solvent content is sufficiently low to preserve said biological material, during sterilization by irradiation, for its intended use following sterilization with radiation, and said biological material is glassy or vitrified.

153. (New) The composition according to claim 152, further comprising at least one additional stabilizer selected from the group consisting of: ascorbic acid or a salt or ester thereof; glutathione; 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; uric acid or a salt or ester thereof; methionine; histidine; N-acetyl cysteine; lipoic acid; sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof; propyl gallate; a mixture of ascorbic acid, or a salt or ester thereof, and uric acid, or a salt or ester thereof; a mixture of ascorbic acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; a mixture of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; and a mixture of uric acid, or a salt or ester thereof and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, wherein said at least one additional stabilizer is present in an amount effective to preserve said biological material for its intended

use following sterilization with radiation.

154. (New) The composition of claim 152, wherein said residual solvent content is less than 15%.

155. (New) The composition of claim 152, wherein said residual solvent content is less than 10%.

156. (New) The composition of claim 152, wherein said residual solvent content is less than 5%.

157. (New) The composition of claim 152, wherein said residual solvent content is less than 2%.

158. (New) The composition of claim 152, wherein said residual solvent content is less than 1%.

159. (New) The composition of claim 152, wherein said residual solvent content is less than 0.5%.

160. (New) The composition of claim 152, wherein said residual solvent content is less than 0.08%.

161. (New) The composition of claim 152, wherein said biological material is selected from the group consisting of monoclonal immunoglobulins, polyclonal immunoglobulins, glycosidases, sulfatases, urokinase, thrombin and Factor VIII.

162. (New) The composition of claim 152, wherein the concentration of said biological material is at least 0.5%.

163. (New) The composition of claim 152, wherein the concentration of said biological material is at least 1%.

164. (New) The composition of claim 152, wherein the concentration of said biological material is at least 5%.

165. (New) The composition of claim 152, wherein the concentration of said biological material is at least 10%.

166. (New) The composition of claim 152, wherein the concentration of said biological material is at least 15%.

167. (New) The composition of claim 152, wherein the concentration of said biological material is at least 20%.

168. (New) The composition of claim 152, wherein the concentration of said biological material is at least 25%.

169. (New) The composition of claim 152, wherein the concentration of said biological material is at least 50%.

170. (New) A method of treating a disease or deficiency in a mammal comprising

administering to a mammal in need thereof an effective amount of a composition according to claim 152.

171. (New) The method according to claim 170, wherein said mammal is a human.

172. (New) The method according to claim 170, wherein said deficiency is Factor VIII deficiency.

173. (New) The method according to claim 170, wherein said disease responds to the administration of urokinase.

174. (New) The method according to claim 170, wherein said disease responds to the administration of thrombin.

175. (New) The method according to claim 170, wherein said deficiency is a glucosidase deficiency.

176. (New) The method according to claim 170, wherein said deficiency is a galactosidase deficiency.

177. (New) The method according to claim 176, wherein said deficiency is a Fabry's Disease.

178. (New) The method according to claim 170, wherein said deficiency is a sulfatase deficiency.

179. (New) The method according to claim 170, wherein said deficiency is an Immunoglobulin deficiency.

180. (New) The method according to claim 170, wherein said disease responds to the administration of an Immunoglobulin.

181. (New) The method according to claim 170, wherein said disease responds to the administration of Factor VIII.